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510(K) SUMMARY

N.E.S.S. NEUROMUSCULAR ELECTRICAL STIMULATION SYSTEMS LTD.

HANDMASTER

Applicant's Name:

N.E.S.S. Neuromuscular Electrical Stimulation Systems Ltd.
19 Ha-Haroshet Street
Kiedar Center, Suite 207
P.O. Box 2500, Industrial Zone
Ra'anana 43465
ISRAEL
Tel: 011-972-9-7485738
Fax: 011-972-9-7485740

Contact Person:

Jonathan S. Kahan, Esq.
Hogan & Hartson, L.L.P.
Columbia Square
555 Thirteenth Street, NW
Washington, DC 20004-1109
Tel: (202) 637-5791
Fax: (202) 637-5910

And/or

Dorit Winitz, Ph. D
Push-med Ltd.
117 Ahuzah St.
Ra'anana 43373, Israel
Tel: 972-9- 7718130
Fax: 972-9-7718131
dorit@push-med.com

Date Prepared:

June, 2003

Trade Name:

HANDMASTER

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Classification Name:

Powered muscle stimulators

Classification:

Class II; Product Code 89IPF;
Regulation No. 890.5850.

Predicate Devices

N.E.S.S. Neuromuscular Electrical Stimulation Systems Handmaster (K952273, K982482, and K010837).

Device Description:

The Handmaster is a portable, one-channel electrical neuromuscular stimulator for personal use. The stimulator serves five surface electrodes held on to the upper limb by a splint. The control unit housing the stimulator may be worn using the shoulder strap provided, or it may be placed on any stable surface. The splint is worn on the hand and forearm. The splint is connected to the control unit by a light cable.

A single channel of constant-voltage symmetrical biphasic Russian waveform stimulation is delivered to the muscles through five surface electrodes. Microprocessor-controlled switching of the stimulation between these five electrodes allows the muscles to be activated in combinations either cyclically or continuously. The stimulation is ramped up at the beginning and down at the end of each cycle.

The electrode locations allow the Handmaster to give finger and thumb extension and flexion. By pressing the Mode button on the Control Unit, the user can select from seven stimulation programs that comprise either cyclic or continuous activation of the finger and thumb extensors and flexors. In addition to the former light glowing presentation of the active mode, the new LCD screen enables also the presentation of the name of active mode and sub-mode. A continuously changing three and two-bar combination indicates that the stimulation phase is active. A "seventh segment like" object indicates the stimulation intensity or the battery condition.

The user can increase or decrease the stimulation intensity in ten discrete levels by pressing on buttons labeled "+" or "-" on the control unit. This alters the duration of the stimulation pulse. The intensity is displayed as a number (0 to 9) on a seven-segment like display.

During the initial system set-up, the clinician opens a screw secured clinical panel within the control unit. Adjustments are provided for limiting the maximum current to the extensor muscles and to the flexor muscles, along with a global timing factor which increases or decreases the duration of the stimulation cycles, effectively speeding or slowing the cyclic hand motion.

The user starts or stops the stimulation program by pressing a "trigger" button. If required, the user may also stop all stimulation immediately by switching OFF the device.

The Handmaster splint is used to hold the wrist joint at a comfortable extension angle (20°), and also to hold the electrodes on the forearm and hand segments. It is constructed from fiber-reinforced plastic with soft polyurethane cushion sections to distribute stress over bony regions. The electrodes are made from metal mesh. Replaceable water-soaked cloth pads are arranged over the electrodes to provide a conductive interface with the skin. A sponge is provided to facilitate wetting of the electrode pads.

Rechargeable nickel-metal-hydride (NiMH) batteries power the device. Battery status can be displayed both during device operation and while recharging the batteries. Both visual and audio battery-low warnings are provided.

Intended Use:

The Handmaster is intended to be used for the following indications: Maintenance or increase of range of motion, reduction of muscle spasm, prevention or retardation of disuse atrophy, muscle reeducation, and increasing local blood circulation. In patients suffering from upper limb paralysis due to C5 spinal cord injury or hemiplegia due to stroke, it is also intended to provide hand active range of motion and hand function.

Performance Data & Substantial Equivalence

The Handmaster device is substantially equivalent in all aspects, e.g., technological characteristics, mode of operation, performance characteristics, intended use, etc., to the commercially available Handmaster devices. The principle changes between the devices include:

- Change of the User Control display from 7-Segment display to a graphic display (LCD) and related changes in hardware and software
- Change of the mechanical ON/OFF switch

- Change in power supply
- Limited changes in the external closure
- Change of the battery
- Change in operating mode combinations
- Change in part of the splint materials

In vitro, biocompatibility, electrical and electromagnetic testing and verification and validation testing of the software were performed to ensure that the modified HANDMASTER does not raise any new questions of safety and efficacy. Based on these tests results, N.E.S.S Ltd. believes that the modified HANDMASTER is substantially equivalent to the cleared HANDMASTER devices, without raising new safety and/or effectiveness issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 8 2003

N.E.S.S. Neuromuscular Electrical Stimulation Systems Ltd.
c/o Mr. Jonathan S. Kahan, Esq.
Hogan & Hartson, L.L.P.
Columbia Square
555 Thirteenth Street, NW
Washington, DC 20004-1109

Re: K031900
Trade/Device Name: HANDMASTER
Regulation Numbers: 21 CFR 882.5810, 890.5850
Regulation Names: External functional neurolmuscular stimulator, Powered muscle stimulator
Regulatory Class: II
Product Codes: GZI, IPF,
Dated: June 18, 2003
Received: July 9, 2003

Dear Mr. Kahan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K031900

Device Name: N.E.S.S. Neuromuscular Electrical Stimulation System HANDMASTER

Indications for Use:

The Handmaster is intended to be used for the following indications: maintenance or increase of range of motion, reduction of muscle spasm, prevention or retardation of disuse atrophy, muscle reeducation, and increasing local blood circulation. In patients suffering from upper limb paralysis due to C5 spinal cord injury or hemiplegic patients due to stroke, it is also intended to provide hand active range of motion and hand function.

(PLEASE DO NOT WRITE BELOW THIS LINE -CONTINUE ON ANOTHER PAGE IF NEEDED)

510(k) Number _____

Prescription Use _____ (Per 21 CFR 801.109) OR Over the Counter Use_____

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

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510(k) Number K031900